

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lustral 50mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Sertraline hydrochloride equivalent to 50mg sertraline.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK

White, capsular-shaped, film-coated scored tablets marked "ZLT-50" on one side and "Pfizer" on the other. The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0822/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/001/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Calcium hydrogen phosphate dihydrate (E341)

Microcrystalline cellulose (E460)

Hydroxypropylcellulose (E463)

Sodium starch glycolate

Magnesium stearate (E572)

Film-coating

Opadry White containing:

Hypromellose (E464)

Titanium dioxide (E171)

Macrogol

Polysorbate 80 (E433)

Opadry Clear containing:

Hypromellose (E464)

Macrogol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Tablets are packed in Aluminium/PVC blisters of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/094/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th March 2013

10 DATE OF REVISION OF THE TEXT

September 2014